(*b*) The gramicidin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*c*) The batch:

(*1*) For all tests except sterility: A minimum of 6 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content.* Proceed as directed in §444.342b(b)(1)(i). The neomycin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) *Gramicidin content.* Proceed as directed in §444.342b(b)(1)(iii). The content of gramicidin is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of gramicidin that it is represented to contain.

(2) *Sterility.* Proceed as directed in §436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use 0.25 milliliter of sample in lieu of 1.0 milliliter.

(3) *pH.* Proceed as directed in §440.80a(b)(5)(ii) of this chapter, using the undiluted sample.

[39 FR 19046, May 30, 1974, as amended at 50 FR 19919, May 13, 1985; 59 FR 8398, Feb. 22, 1994]

§444.342d Neomycin sulfate-polymyxin B sulfate ———— ophthalmic suspension (the blank being filled in with the established name(s) of the other active ingredient(s) present in accordance with paragraph (a)(1) of this section).

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* The drug is a suspension in a suitable and harmless aqueous vehicle containing, in each milliliter, neomycin sulfate, polymyxin B sulfate, and other active ingredients in the following amounts:

(i) 3.5 milligrams of neomycin, 16,250 units of polymyxin B, and either 5 milligrams or 15 milligrams of hydrocortisone acetate; or

(ii) 5 milligrams of neomycin, 15,000 units of polymyxin B, and 2.5 milligrams of hydrocortisone; or

(iii) 3.5 milligrams of neomycin, 10,000 units of polymyxin B, and 10.0 milligrams of hydrocortisone; or

(iv) 3.5 milligrams of neomycin, 10,000 units of polymyxin B, and 5.0 milligrams of prednisolone acetate.

It contains suitable and harmless buffers, dispersants, irrigants, and preservatives. It is sterile. Its pH is not less than 5.0 and not more than 7.0; except if it contains 10 milligrams per milliliter of hydro–cortisone, its pH is not less than 4.1 and not more than 7.0. The neomycin sulfate used conforms to the standards prescribed by §444.42a(a)(1)(i), (vi), and (vii). The polymyxin B sulfate used conforms to the standards prescribed by §448.30a(a)(1)(i), (vi), (vii), and (ix) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate used in making the batch for potency, pH, and identity.

(*b*) The polymyxin B sulfate used in making the batch for potency, pH, residue on ignition, and identity.

(*c*) The batch for neomycin content, polymyxin content, sterility, and pH.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The batch for:

(*1*) All tests except sterility: A minimum of 6 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content.* Proceed as directed in § 444.42a(b)(1) except prepare the sample as follows: Remove an accurately measured representative portion of the sample with a suitable syringe, place into an appropriate volumetric flask to yield a convenient stock solution. Dilute to volume with 0.1*M* potassium phosphate buffer, pH 8.0. Further dilute with 0.1 *M* potassium phosphate buffer, pH 8.0, to the proper prescribed reference concentration. Its content of neomycin is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) *Polymyxin content.* Remove an accurately measured representative portion with a suitable syringe, dilute to a convenient concentration with 10 percent potassium phosphate buffer, pH 6.0. Further dilute to a concentration of 10 units of polymyxin per milliliter with 10 percent potassium phosphate buffer, pH 6.0, and proceed as directed in § 448.30a(b)(1) of this chapter, except add to each concentration of the polymyxin standard curve a quantity of neomycin to yield the same concentration of neomycin as that present when the sample is diluted to contain 10 units of polymyxin per milliliter. Its content of polymyxin is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin that it is represented to contain.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except if the steroid prevents solubilization, use 0.25 milliliter of sample in lieu of 1 milliliter and proceed as directed in paragraph (e)(2) of that section.

(3) *pH.* Proceed as directed in § 440.80a(b)(5)(ii) of this chapter, using the undiluted sample.

[39 FR 19045, May 30, 1974, as amended at 42 FR 37975, July 26, 1977; 47 FR 23441, May 28, 1982; 49 FR 5097, Feb. 10, 1984; 49 FR 34351, Aug. 30, 1984; 50 FR 19919, May 13, 1985; 59 FR 8399, Feb. 22, 1994]

§ 444.342e Neomycin sulfate ointment; neomycin sulfate- ———— ointment (the blank being filled in with the established name(s) of certain other active ingredient(s)).

The requirements for certification and the tests and methods of assay for neomycin sulfate ointment and for neomycin sulfate- ———— ointment are described in § 444.542a.

§ 444.342f Neomycin sulfate-gramicidin topical ointment; neomycin sulfate-gramicidin-triamcinolone acetonide ointment; neomycin sulfate-gramicidin-fludrocortisone acetate ointment.

The requirements for certification and the tests and methods of assay for neomycin sulfate-gramicidin topical ointment; neomycin sulfate-gramicidin-triamcinolone acetonide ointment; neomycin sulfate-gramicidin-fludrocortisone acetate ointment are described in § 444.542f.

§ 444.342g Neomycin sulfate-hydrocortisone acetate ophthalmic suspension; neomycin sulfate-prednisolone acetate ophthalmic suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-hydrocortisone acetate ophthalmic suspension is an aqueous suspension containing in each milliliter 3.5 milligrams of neomycin and 5 milligrams or 15 milligrams of hydrocortisone acetate. Neomycin sulfate-prednisolone acetate ophthalmic suspension is an aqueous suspension containing in each milliliter 3.5 milligrams of neomycin and 2.5 milligrams of prednisolone acetate. The vehicle contains one or more suitable and harmless buffers, preservatives, and dispersants. It is sterile. Its